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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/553,683

04/21/2000

Lawrence Xavier Webb, M.D.

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04/08/2008

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EXAMINER

SMITH, RUTH S

ART UNIT

PAPER NUMBER

3737

NOTIFICATION DATE

DELIVERY MODE

04/08/2008

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/553,683
Filing Date: April 21, 2000
Appellant(s): WEBB, M.D., LAWRENCE XAVIER

Nancy M. Lambert
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 4, 2007 appealing from the Office action mailed March 8, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,899,762	MULLER	2-1990
5,052,035	KRUPNICK	9-1991
5,260,985	MOSBY	11-1993

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 30, 32, 34-38, 41-43, 47-49, 53-57, 61, 67 and 71-75 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Muller '762 in view of Krupnick '035. Muller '762 teach all the features of the instant invention including a drape with radio-opaque grid lines 53 which are vertical and horizontal (see col. 6, lines 18-36) which are uniquely identifiable by letters and numbers as indicated by Figure 1. Adhesive is provided on a major portion of the drape (see col. 5, lines 15-18). Muller '762 does not teach the use of imaging technology wherein a pattern is obtained corresponding to the

radio-opaque labels on the surgical drape. In the same field of endeavor, Krupnick '035 teaches the use of imaging technology wherein a pattern is obtained corresponding to the radio-opaque labels on the surgical drape (see Figure 4 and see col. 5, lines 5-16). Krupnick '035 also teaches a cutout through the grid lines to effectuate a biopsy (see Figure 2 and see col. 5, lines 17-31). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Muller '762 to incorporate the teachings of Krupnick '035 in order to utilize imaging to more correctly identify the area for biopsy (motivation to combine provided by Krupnick '035 in col. 5, lines 15-16, reciting that imaging technology through the radio-opaque flexible substrate expedites localization of the area of interest). The Appellant argued that there is criticality because of the potential advantage of unique labels as facilitating surgery (citing specification p. 19, lines 11-29). As previously stated in the same paragraph, in the last sentence, it is stated that if the squares are too small then the unique identifiers can be placed in the margins, thereby clearly indicating the Examiner's argument of lack of criticality and alternative functional equivalency. With respect to the cutout, in the broadest reasonable interpretation the Examiner's position is that when a biopsy needle enters the surgical drape there is necessarily a cutout. Finally the addition of the sterile limitation is inherent in any medical procedure in order to avoid contamination of the surgical field.

Claims 39-40, 44-46, 50-52 and 52-57, 59, 61-66, 68-70 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Muller '762 in view of Krupnick '035 and Mosby '985. Muller '762 in view of Krupnick '035 teach all the features of the instant invention as set forth above, except for the use of radio-opaque circles and utilization of pliable material for use on breast procedures or on body parts resembling cylindrical or conical configurations such as a finger. Mosby '985 teaches the use of radio-opaque circles and utilization of pliable material for use on breast procedures or on body parts resembling cylindrical or conical configurations such as a finger (see col. 5, lines 7-12; col. 6, lines 38-47 and col. 7, lines 1-10). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Muller '762 in view of Krupnick '035 to incorporate the teaching of Mosby '985 when using the drape during

biopsy procedures of areas such as the breast or the finger to more readily localize the area of interest for biopsy using circular radio-opaque indications. The Appellant argued that there is criticality because of the potential advantage of unique labels as facilitating surgery (citing specification p. 19, lines 11-29). As previously stated in the same paragraph, in the last sentence, it is stated that if the squares are too small then the unique identifiers can be placed in the margins, thereby clearly indicating the Examiner's argument of lack of criticality and alternative functional equivalency. With respect to the cutout, in the broadest reasonable interpretation the Examiner's position is that when a biopsy needle enters the surgical drape there is necessarily a cutout. Finally the addition of the sterile limitation is inherent in any medical procedure in order to avoid contamination of the surgical field.

(10) Response to Argument

With respect to the limitation of "a plurality of uniquely labeled intersections" that are "in the interior of the radio-opaque pattern," The Appellant argued that there is criticality because of the potential advantage of unique labels as facilitating surgery (citing specification p. 19, lines 11- 29). However, in the same paragraph cited by the Appellant, in the last sentence, it is stated that if the squares are too small then the unique identifiers can be placed in the margins, as taught by both Muller '762 and Krupnick '035 (please see Figure 1 of each of the respective references) thereby clearly indicating the Examiner's argument of lack of criticality and the validity of alternative functional equivalency. With respect to the lack of the teaching of a "sterile drape", please see for example Figure 4 of Muller '762 clearly indicating the antiseptic material of the drape (also please see Abstract, last sentence; col. 3, lines 57-62; col. 6, lines 6-17; col. 7, lines 42-51; and col. 9, lines 5-9). With respect to the lack of the teaching of a "cutout", Krupnick '035 teaches a cutout through the grid lines to effectuate a biopsy (see Figure 2 and see col. 5, lines 17-31) by creating an opening 40. Numeral 26 of Figure 2 indicates the line extending outward from the cutout. Furthermore, in the alternative, according to the broadest reasonable interpretation, the biopsy needle itself will inherently create a cutout through the drape when it penetrates and exits the drape. In other words, either the drape is cutout and the biopsy needle is inserted through the

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patient or the needle itself will cut through the drape creating a cutout when it penetrates and exits the drape.

Finally, with respect to the argument that Mosby '985 does not explicitly teach application of the drape on a finger, Mosby '985 teaches the use of radio-opaque circles and utilization of pliable material for use on breast procedures or on body parts resembling cylindrical or conical configurations such as a finger (see col. 5, lines 7-12; col. 6, lines 38-47 and col. 7, lines 1-10). Also see col. 6, line 54, referring to "human body parts" for possible application of the Mosby '985 invention. Therefore, the drape is capable of being used at any body part of interest, which resembles cylindrical or conical configurations such as the finger.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Ruth S. Smith/
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